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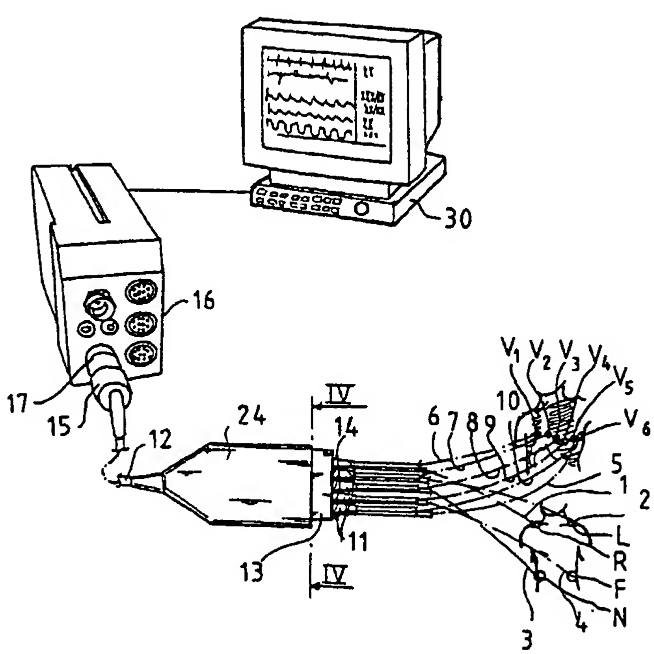
(54) Title: SYSTEM FOR ECG MONITORING



(57) Abstract: The invention concerns a system for ECG monitoring. The system comprises signal leads (1 - 10) connected to corresponding measuring electrodes (R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6), which are attached to a patient (P) in accordance with the standard electrode placement, each of said signal leads being provided with a first connector element (11); a collecting connector (13) containing second connector elements (14) for receiving the first connector elements (11); and an ECG apparatus comprising an amplifier unit (16) to which the measurement signals are passed from the collecting connector. The number of second connector elements (14; 14_1, 14_2) in the collecting connector (13) is at most a number corresponding to the maximum number of measuring electrodes defined in the ECG standard; and the system comprises change-over switches (18 - 22) which are so implemented that, in a first connection position (I), they will conduct the measurement signals from the measuring electrodes (R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6) attached to the patient (P) to the ECG apparatus so that the corresponding signal leads (1-10) have no shielding ground connection, while in a second connection position (II) they establish a shielding ground connection for certain signal leads.

WO 01/06923 A1

SYSTEM FOR ECG MONITORING

The present invention relates to a system as defined in the preamble of claim 1.

In prior art, a system for ECG monitoring as represented by the diagrams in Fig. 1 and 2 is known. If Fig. 1, the same patient P is diagrammatically represented by two pictures of the torso, where the lower picture shows a standard four-point placement of measuring electrodes R, L, N and F (so-called limb electrodes) for an impedance respiration measurement. For the sake of clarity, the upper picture separately shows a standard placement of ECG measuring electrodes V_1, V_2, V_3, V_4, V_5, V_6 on the patient's thorax. Together, R, L, N, F and V_1, V_2, V_3, V_4, V_5, V_6 form a so-called 12-lead connection system. A so-called 5-lead connection system also used in ECG measurement consists of electrodes R, L, N, F, V_5.

A 12-lead connection system as presented in Fig. 1 and 2 comprises 1 - 10 signal leads, which are connected to corresponding measuring electrodes R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6 as mentioned above, attached to the patient P according to standard electrode placement. Each signal lead 1 - 10 is provided with a first connector element 11. The system further comprises a collecting cable 12 with an adapter 24 at its end. The adapter 24 comprises a collecting connector 13 provided with second connector elements 14 for receiving the first connector elements 11 of the signal lead. At the other end of the cable 12 is a third connector element 15. The system further comprises an ECG apparatus 30, which comprises an amplifier unit 16. The amplifier unit 16 is provided with a fourth connector element 17, to which the third connector element 15 of the collecting cable 12 is connected.

ECG monitoring and diagnostic so-called 12-lead ECG have traditionally been performed using different sets of equipment. Monitoring was performed as

a continuous process using 3-lead or 5-lead equipment and 12-lead monitoring was generally performed when necessary under the supervision of a cardiologist as a short separate operation. However, it is possible to build an apparatus using modern electronics which brings the price of 12-lead ECG to a reasonable level, thus making it sensible to use continuous 12-lead monitoring. However, 12-lead equipment is more complicated than 5-lead equipment as it needs ten measuring electrodes as mentioned above: R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6, and therefore also ten patient cables, i.e. signal leads 1 - 10 from the amplifier to the patient's skin. The end of the shielded collecting cable 12 in the prior-art 12-lead system is overloaded with a collecting connector 13, which is also presented in Fig. 2 as a diagram showing it in an end view. It comprises twenty connector elements 14 in all. Placed in the upper row on the right are circular connector elements 14 for the connector elements 11 of the signal leads 1 - 5 coming from the limb electrodes R, L, N, F and one thorax electrode V_5. Connected to the circular connector elements 14_1 in the left-hand part of the upper row are the connector elements 11 of the signal leads 6 - 10 coming from the thorax electrodes V_1, V_2, V_3, V_4 and V_6. The shield of each signal lead 1 - 10 is connected to one of the rectangular connectors in the lower row (connections consistent with the AAMI standard), which are connected to a floating ground G.

Grounding of the shields of the signal leads has an importance especially in ECG monitoring performed during anesthesia, because surgical operations are often performed using a so-called diathermic device, i.e. an electric surgical knife, whose high-frequency electric current would otherwise confuse the ECG monitoring process.

The figure also shows protective resistors 23, whose function is to protect the amplifier elec-

tronics against the high-voltage pulse of a defibrillator. Two resistors are provided for each one of leads 1 - 5 because in most cases, in addition to ECG measurement, the patient's respiration also needs to be monitored, which is done using a parallel apparatus measuring thorax impedance.

The problem with the prior-art system is that, in a 12-lead system, the collecting adapter is a very wide, large and heavy component when traditional, standardized shielded signal leads are used, in which each conductor runs inside a separate shield. The large size and weight are a problem in respect of usability, because the aforesaid collecting adapter is usually placed near the patient and can easily be dropped to the floor, where the adapter and the leads connected to it may be damaged.

The object of the invention is to eliminate the problems referred to above.

A specific object of the invention is to disclose a system which can work both as a 5-lead system and as a 12-lead system and in which it is possible to combine a 5-lead and a 12-lead amplifier connector and signal leads, allowing the same amplifier unit to function alternatively in a 5-lead system with shielded leads or in a 12-lead system with unshielded leads.

A further object of the invention is to disclose a system in which a small and light-weight collecting adapter can be used.

As for the features characteristic of the invention, reference is made to the claims presented below.

According to the invention, the number of second connector elements in the collecting connector is at most a number corresponding to maximum the number of measuring electrodes defined in the ECG standard. The system comprises change-over switches, which

are so implemented that, in a first connection position, they will conduct the measurement signals from the measuring electrodes attached to the patient to the ECG apparatus so that the corresponding signal leads have no shielding ground connection while in a second connection position they establish a shielding ground connection to a so-called floating ground for certain signal leads.

Shielding is not necessarily needed in all monitoring situations, so it is possible to use signal leads without a shielding ground connection.

In an embodiment of the system, the collecting connector is placed in the amplifier unit, and the signal leads are connected directly from the patient to the amplifier unit.

In an embodiment of the system, the system comprises a collecting cable between the signal leads and the amplifier unit. In this case, the collecting connector is connected to the collecting cable.

In an embodiment of the system, the collecting connector comprises a number of second connector elements corresponding to the number of measuring electrodes defined in the 12-lead ECG standard.

In an embodiment of the system, the change-over switches in their second connection position establish a shielding ground connection for a first group of signal leads via the connector elements in the collecting connector intended for a second group of signal leads.

In an embodiment of the system, the measuring electrodes are connected to the patient in accordance with the 12-lead ECG standard. In this case, in order to accomplish a 12-lead ECG measurement, the change-over switches are in the said first position to pass the measurement signals from all measuring electrodes to signal processing in the ECG apparatus, the signal leads now having no shielding ground connection.

In an embodiment of the system, the measuring electrodes are connected to the patient in accordance with the 5-lead ECG standard. In this case, to accomplish a 5-lead ECG measurement with grounded shielding, the change-over switches are in the said second position, the first group of signal leads now having a shielding ground connection to a floating ground.

In an embodiment of the system, the second connector elements in the collecting connector are arranged in two adjacent rows, where the second connector elements in one row are disposed in paired alignment with the connector elements in the other row.

In an embodiment of the system, the change-over switches are disposed in the amplifier unit.

In an embodiment of the system, the change-over switches are controllable analog switches.

In an embodiment of the system, the system comprises a control device for the control of the change-over switches.

In an embodiment of the system, the control device comprises means allowing the change-over switches to be controlled by the user.

In an embodiment of the system, the control device comprises detection means so implemented that they will automatically detect whether the measuring electrodes are connected to a patient; and means for selecting the connection position of the change-over switches on the basis of this detection.

In an embodiment of the system, the detection means are so implemented that they will automatically detect connection of the measuring electrodes to a patient by measuring the resistance of the measuring electrodes.

In an embodiment of the system, the detection means are so implemented that they will automatically identify the signal lead types used, by measuring the

capacitances regardless of whether the leads are connected to a patient or not.

In the following, the invention will be described in detail by the aid of a few examples of its embodiments with reference to the attached drawing, wherein

Fig. 1 is a diagrammatic representation of prior-art system,

Fig. 2 is a diagrammatic representation of prior-art collecting connector as seen from direction II-II in Fig. 1, and a diagram of the prior-art system,

Fig. 3 presents a diagram representing a first embodiment of the system of the invention,

Fig. 4 presents a diagram representing a second embodiment of the system of the invention,

Fig. 5 presents a diagram representing a collecting connector as seen from direction II-II in Fig. 3 or 4, as well as a diagram of the system.

Fig. 3 presents an ECG monitoring system comprising signal leads 1 - 10, which are connected in accordance with the standard electrode placement to corresponding measuring electrodes R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6 attached to the patient P. Each signal lead 1- 10 is provided with a first connector element 11. One end of the collecting cable 12 is provided with an adapter 24 comprising a collecting connector 13. The collecting connector 13 contains second connector elements 14, to which the first connector elements 11 of the signal leads are connected. The other end of the collecting cable 12 is provided with a third connector element 15. The ECG apparatus comprises an amplifier unit 16, which is provided with a fourth connector element 17, to which the third connector element 15 is connected.

Fig. 4 presents a second preferred embodiment of the system, which corresponds to the embodiment in

Fig. 3 except that no collecting cable is used at all; instead, the signal leads 1 - 10 are taken directly from the patient P to the amplifier unit 16, which is provided with a collecting connector 13. The collecting connector 13 is of a kind corresponding to the collecting connector at the end of the collecting cable in the embodiment in Fig. 3. In the following, the connector and the connections in it will be described in detail with reference to Fig. 5.

As shown in Fig. 5, the collecting connector 13 in the embodiments presented in Fig. 3 and 4 contains a number of second connector elements 14; 14_1, 14_2 corresponding to the number of measuring electrodes defined in the 12-lead ECG standard, i.e. a total of 10 connector elements. The electronics of the amplifier unit 16 is provided with analog change-over switches 18 - 22 controllable by the microprocessor of the ECG apparatus 30. The change-over switches have two connection positions I and II. In the first connection position I, the measurement signals are passed from all the measuring electrodes R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6 connected to the patient P to the ECG apparatus in such manner that the corresponding signal leads 1 - 10 have no shielding ground connection. In the second connection position II (depicted with a broken line in Fig. 5), the change-over switches 18 - 22 have been turned to a position in which they establish a shielding ground connection to a so-called floating ground G for certain signal leads. In the second connection position II, the change-over switches 18 - 22 establish a shielding ground connection for the first group 1 - 5 of signal leads via the second connector elements 14_2 in the collecting connector 13 intended for the second group 6 - 10 of signal leads.

Both in 5-lead and in 12-lead ECG monitoring, a conventional existing collecting connector designed

for a 5-lead system can be used, which means in practice that the shield connections 14_2 of the 5-lead system are utilized by the thorax electrodes V_1, V_2, V_3, V_4, V_6 of the 12-lead system. In the 12-lead measuring mode, the existing signal leads are used without shielding earth connections, whereas in the 5-lead measuring mode the existing signal leads are used with shielding earth connections. The required essential change is the provision of change-over switches 18 - 22 in the electronics of the amplifier unit 16.

In Fig. 5, the change-over switches 18 - 22 are in position I, depicted with a solid line, to allow a 12-lead ECG measurement to be carried out. The measuring electrodes R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6 are connected to the patient in accordance with the 12-lead ECG standard. The measurement signals are conducted by signal leads 1 - 10 without a shielding ground connection via all ten connector elements 14_1 and 14_2 in the collecting connector 13 to the amplifier unit 16 and further in a conventional manner to a signal processing stage in the ECG apparatus.

Alternatively, when the change-over switches 18 - 22 are in position II, depicted with a broken line in Fig. 5, the measurement signals are conducted from the measuring electrodes R, L, N, F, V_5 placed on the patient in accordance with the 5-lead ECG standard via the five second connector elements 14_1 in the upper row of signal leads 1 - 5 in the collecting connector 13 to the amplifier unit 16 and further in a conventional manner to a signal processing stage in the ECG apparatus, and the signal leads 1 - 5 are shielded by a floating ground through the second connector elements 14_2 in the lower row as these are now connected via the change-over switches 18 - 22 to a floating ground G. In this case, the second group 6 - 10 of signal leads may be simultaneously connected to the connector elements 14_2 in the lower row or not: in

any case, no signals are now passed through them to the amplifier or to the ECG apparatus.

The second connector elements 14_1 and 14_2 have been arranged in the collecting connector 13 in two adjacent rows, in which the second connector elements 14_1 and 14_2 are in alignment with each other.

The system preferably comprises a control device, e.g. software means provided in the microprocessor of the ECG apparatus, for the control of the change-over switches 18 - 22. The change-over switches 18 - 22 may either be controllable by the user or they may be controlled by an automatic system. The control device may also comprise detection means for automatically detecting whether the measuring electrodes are connected to a patient or not. The connection position I or II of the change-over switches 18 - 22 can then be selected on the basis of this detection. The automatic system may also be so implemented that it will detect connection of the measuring electrodes to a patient by measuring the resistance of the measuring electrodes, and that, if the resistance is lower than a predetermined limit value, it will detect a disconnected state of the electrode (conventional 'leads-off' detection using a high-resistance pull-up resistor). A more accurate detection of the disconnected state for the selection of an ECG measuring mode can be accomplished by measuring the capacitance exceeding a limit value between the shield and the core of the signal lead, in which case detection will be possible regardless of whether the leads are connected to a patient or not.

The invention is not restricted to the examples of its embodiments described above; instead, many variations are possible within the scope of the inventive idea defined in the claims.

CLAIMS

1. System for ECG monitoring, comprising

- signal leads (1 - 10) connected to corresponding measuring electrodes (R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6) attached to a patient (P) in accordance with the standard electrode placement, each of said signal leads being provided with a first connector element (11),

- a collecting connector (13) containing second connector elements (14) for receiving the first connector elements (11), and

- an ECG apparatus comprising an amplifier unit (16) to which the measurement signals are passed from the collecting connector, characterized in that the number of second connector elements (14; 14_1,14_2) in the collecting connector (13) is at most a number corresponding to the maximum number of measuring electrodes defined in the ECG standard; and that the system comprises change-over switches (18 - 22) which are so implemented that, in a first connection position (I), they will conduct the measurement signals from the measuring electrodes (R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6) attached to the patient (P) to the ECG apparatus so that the corresponding signal leads (1 - 10) have no shielding ground connection, while in a second connection position (II) they establish a shielding ground connection for certain signal leads.

2. System as defined in claim 1, characterized in that the system comprises a collecting cable (12) between the signal leads (1 - 10) and the amplifier unit (16); and that the collecting connector (13) is connected to the collecting cable.

3. System as defined in claim 1, characterized in that the collecting connector (13) is placed in the amplifier unit (16), in which case the signal leads (1 - 10) are passed directly from the patient to the amplifier unit.

4. System as defined in any one of claims 1 - 3, characterized in that the collecting connector (13) has a number of second connector elements (14_1, 14_2) corresponding to the number of electrodes defined in the 12-lead ECG standard.

5. System as defined in any one of claims 1 - 4, characterized in that the change-over switches (18 - 22) in their second connection position (II) establish a shielding ground connection for a first group of signal leads (1 - 5) via the connector elements (14_2) in the collecting connector (13) intended for a second group of signal leads (6 - 10).

6. System as defined in any one of claims 1 - 5, characterized in that the measuring electrodes (R, L, N, F; V_1, V_2, V_3, V_4, V_5, V_6) are connected to the patient in accordance with the 12-lead ECG standard, and that, to accomplish a 12-lead ECG measurement, the change-over switches (18 - 22) are in the said first position (I) to pass the measurement signals from all the measuring electrodes to signal processing in the ECG apparatus, the signal leads (1 - 10) now having no shielding ground connection.

7. System as defined in any one of claims 1 - 6, characterized in that the measuring electrodes (R, L, N, F, V_5) are connected to the patient in accordance with the 5-lead ECG standard, and that, to accomplish a 5-lead ECG measurement with grounded shielding, the change-over switches (18 - 22) are in the said second position (II), the first group of signal leads (1 - 5) now having a shielding ground connection to a floating ground.

8. System as defined in any one of claims 1 - 7, characterized in that the second connector elements (14) in the collecting connector (13) are arranged in two adjacent rows, where the second connector elements (14_1) in one row are disposed in

paired alignment with the connector elements (14_2) in the other row.

9. System as defined in any one of claims 1 - 8, characterized in that the change-over switches (18 - 22) are disposed in the amplifier unit (16).

10. System as defined in any one of claims 1 - 9, characterized in that the change-over switches (18 - 22) are controllable analog switches.

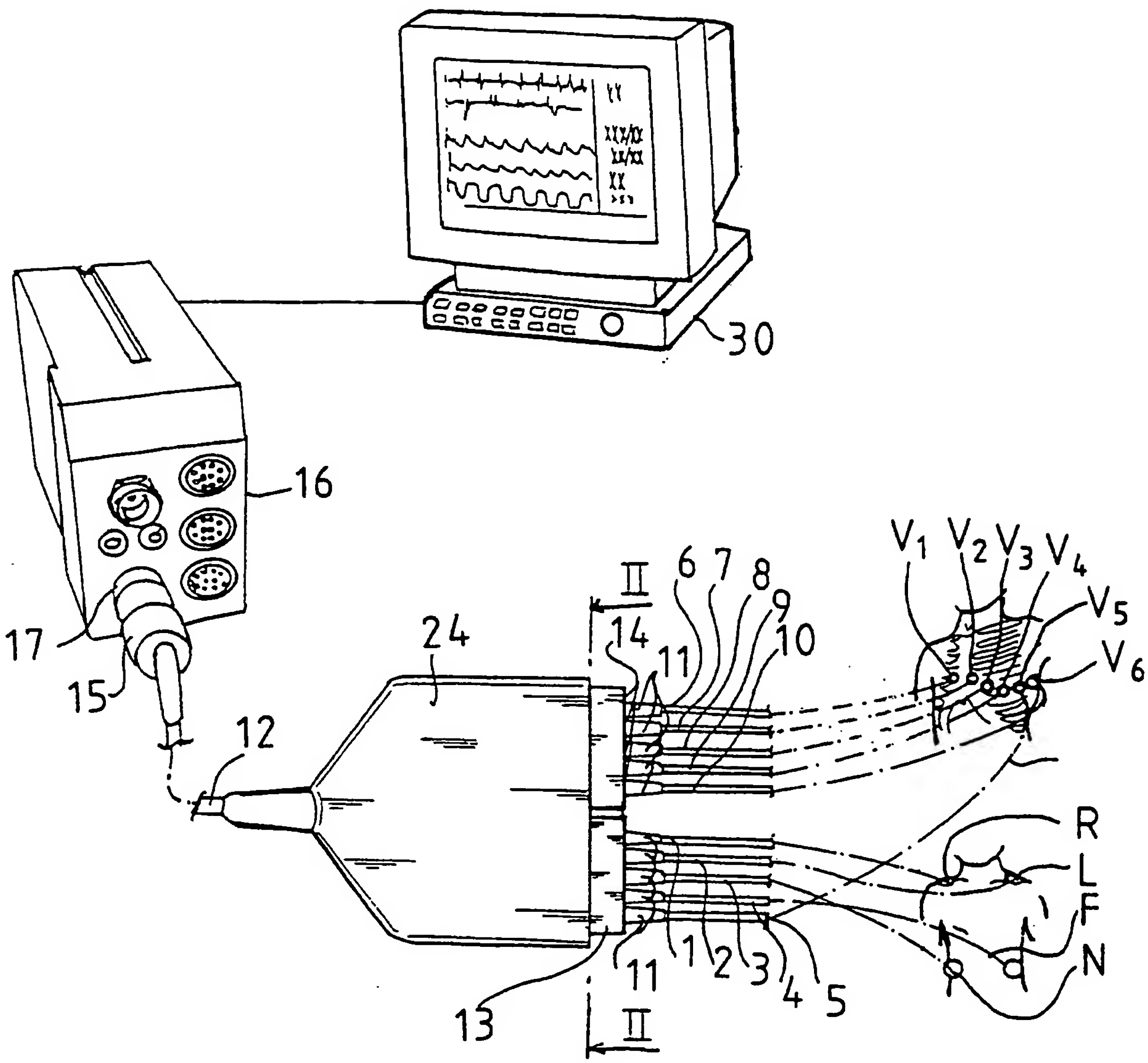
11. System as defined in any one of claims 1 - 10, characterized in that the system comprises a control device for the control of the change-over switches (18 - 22).

12. System as defined in claim 11, characterized in that the control device comprises means allowing the change-over switches (18 - 22) to be controlled by the user.

13. System as defined in claim 11 or 12, characterized in that the control device comprises detection means so implemented that they will automatically detect the connection of the measuring electrodes to a patient; and means for selecting the connection position (I or II) of the change-over switches (18 - 22) on the basis of this detection.

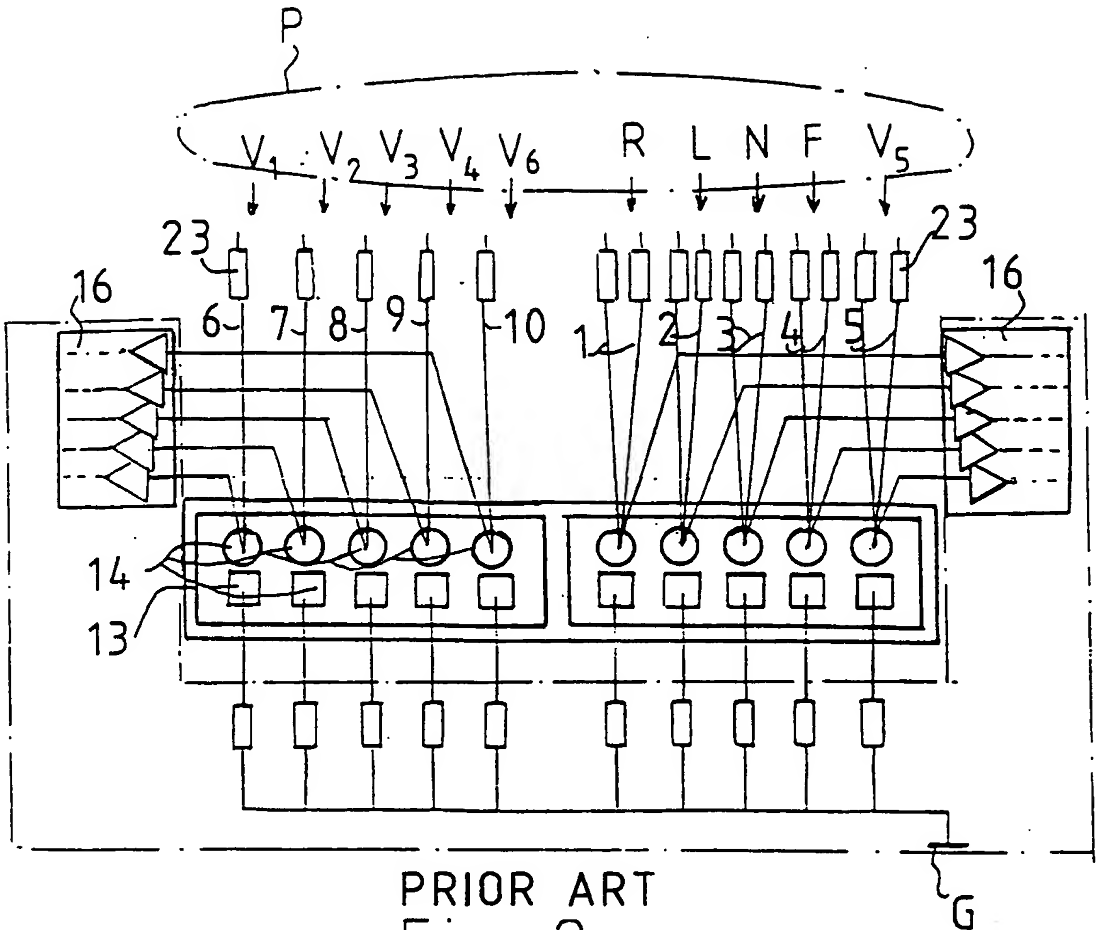
14. System as defined in claim 13, characterized in that the detection means are so implemented that they will automatically detect the connection of the measuring electrodes to a patient by measuring the resistance of the measuring electrodes.

15. System as defined in claim 13 or 14, characterized in that the detection means are so implemented that they will automatically identify the signal lead types used, by measuring the capacitances regardless of whether the leads are connected to a patient or not.



PRIOR ART

Fig 1



PRIOR ART
Fig 2

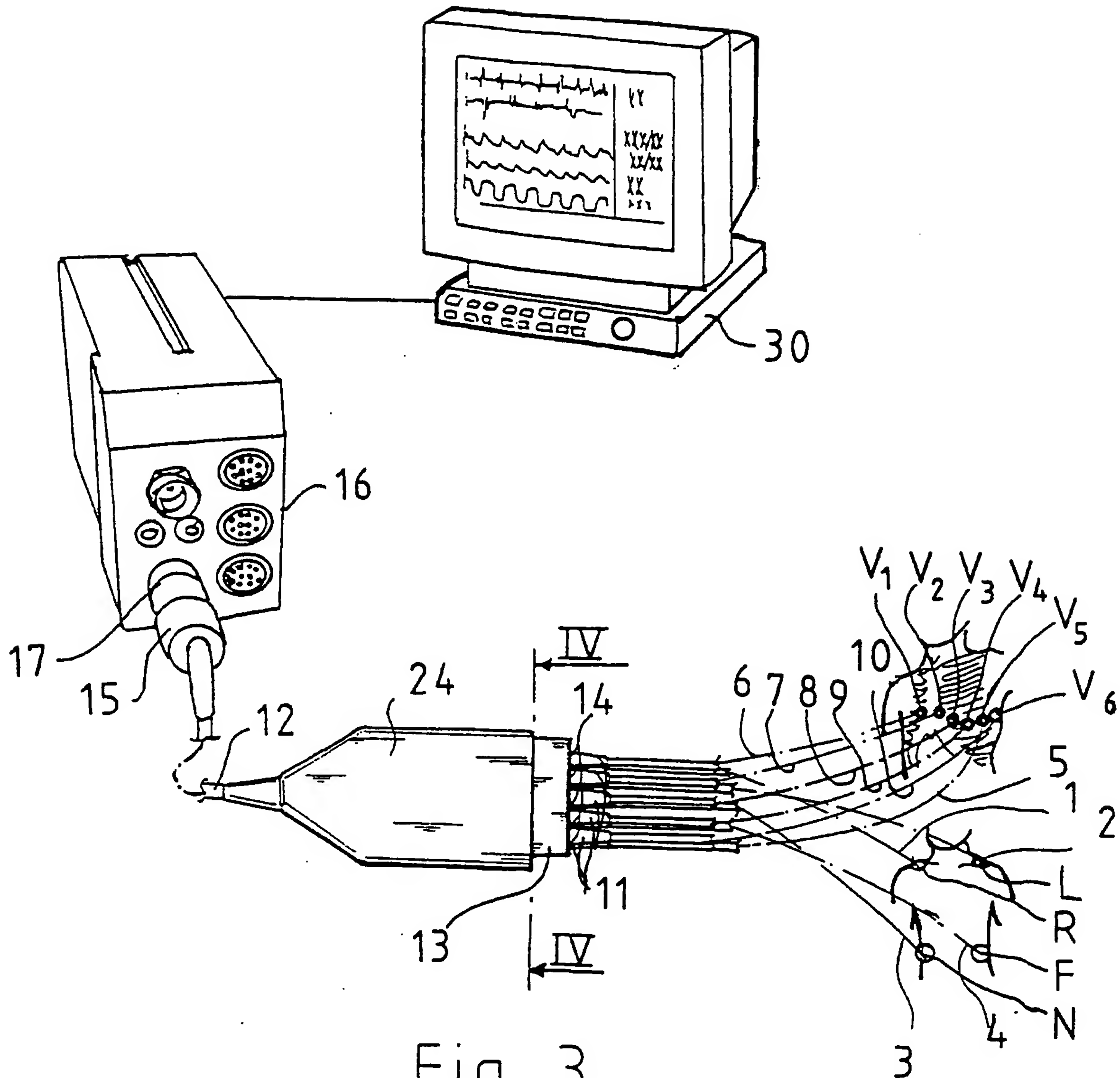


Fig 3

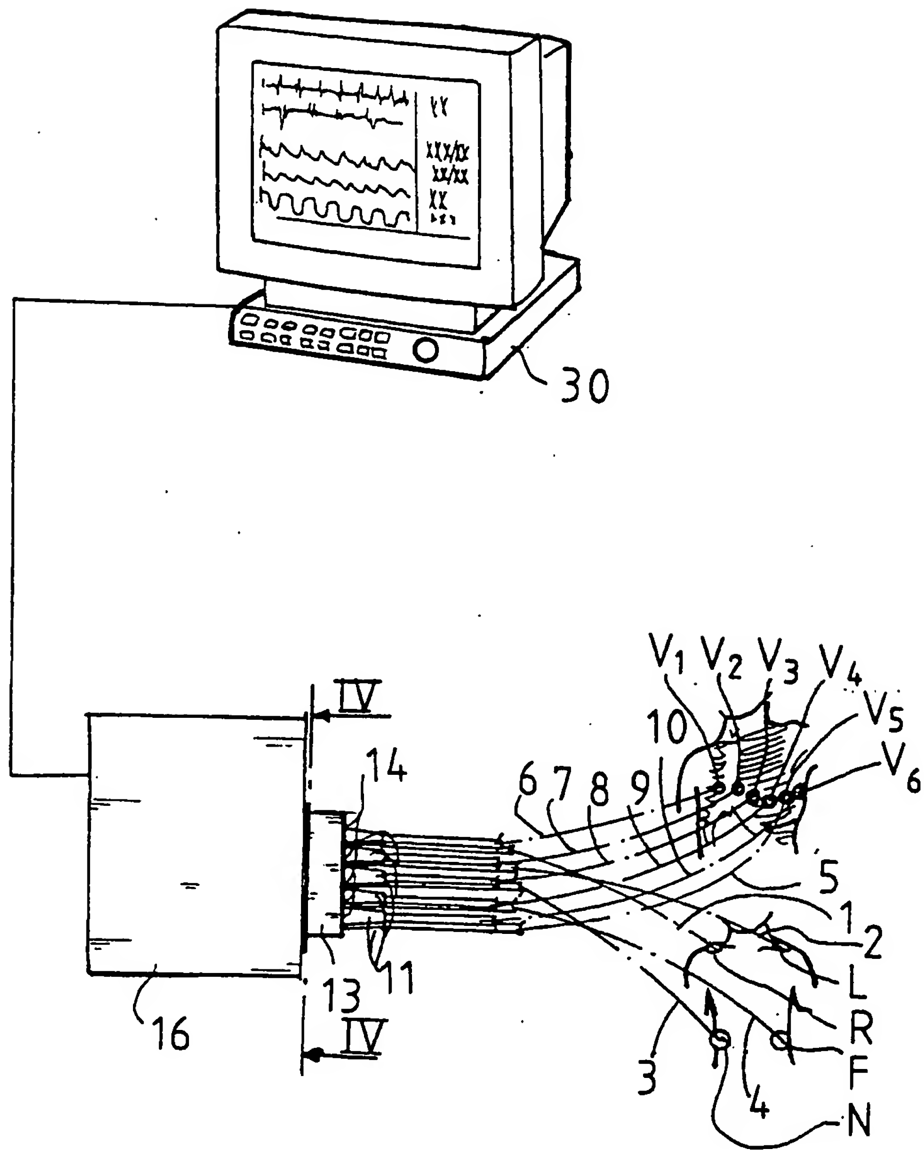


Fig 4

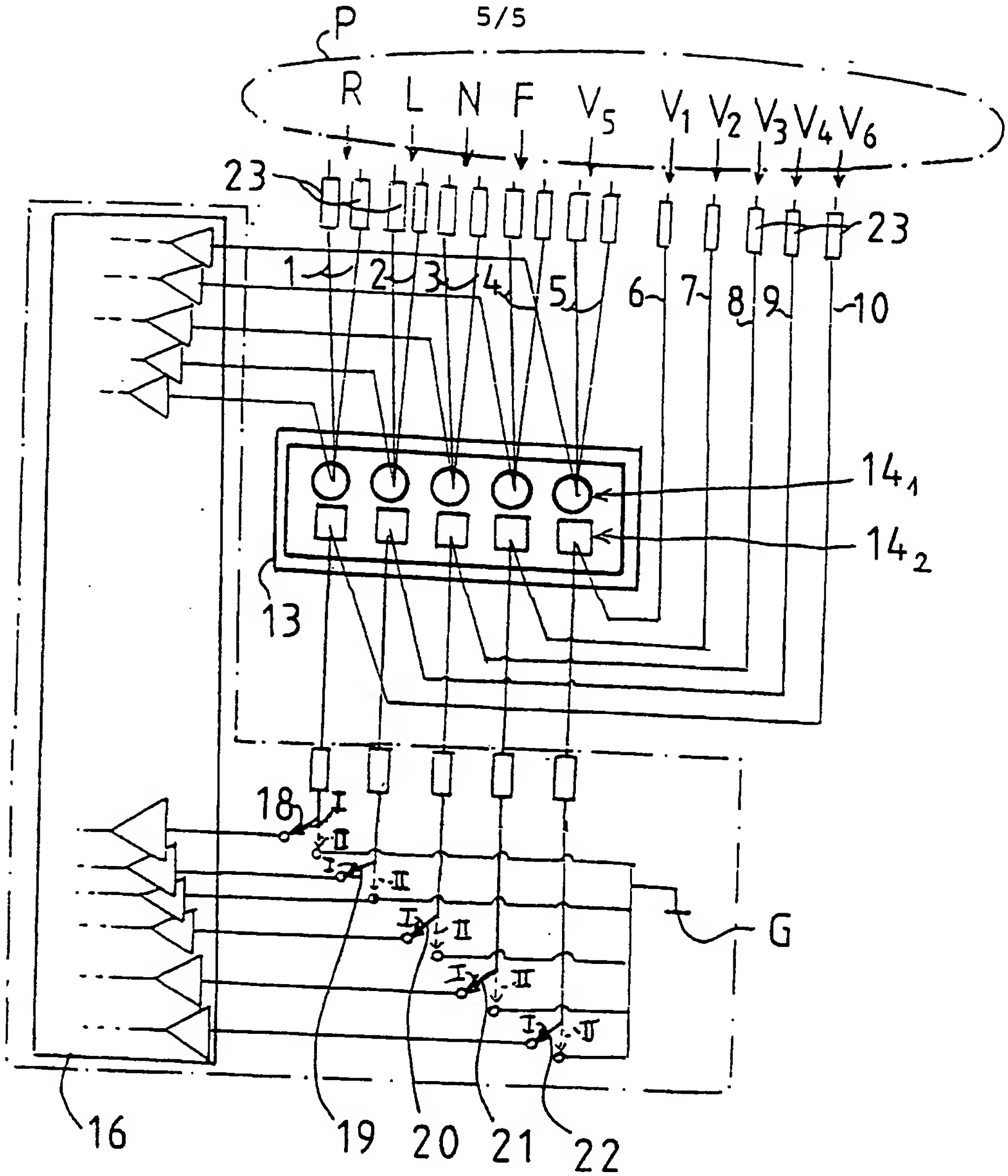

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Fig 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 00/00617

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/0428

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	WO 9614016 A1 (PHYSIO-CONTROL CORPORATION), 17 May 1996 (17.05.96), page 3, line 33 - page 5, line 34	1-12
Y		13-15
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Y	EP 0835635 A1 (JOHNSON & JOHNSON MEDICAL INC.), 15 April 1998 (15.04.98), column 16, line 44 - column 8, line 56	13-15
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X	US 5341812 A (M.J. ALLAIRE ET AL.), 30 August 1994 (30.08.94), column 4, line 17 - column 5, line 33, figure 1	1-8
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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" erlier document but published on or after the international filing date

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Date of the actual completion of the international search 24 October 2000	Date of mailing of the international search report 27-10-2000
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 00/00617

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 4696527 A (W. DING ET AL.), 29 Sept 1987 (29.09.87), figures 1,2, abstract --	1-15
A	WO 9714358 A1 (ASPECT MEDICAL SYSTEMS, INC.), 24 April 1997 (24.04.97), figure 1, abstract -- --------	1-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

03/10/00

International application No.

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